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| 10/532,518  | 04/25/2005  | Thomas Dunker        | Dunker, T. ET AL - 1 PCT | 6031             |
| 25889 7590 09/15/2008<br>COLLARD & ROE, P.C.<br>1077 NORTHERN BOULEVARD<br>ROSLYN, NY 11576 |             |                      |                          |                  |
| EXAMINER<br>STOUT, MICHAEL C  |             |                      |                          |                  |
| ART UNIT  |             | PAPER NUMBER         |                          |                  |
| 3736  |             |                      |                          |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/532,518

**Applicant(s)**

DUNKER ET AL.

**Examiner**

MICHAEL C. STOUT

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This detailed action is in regards to United States Patent Application 10/532518 filed 25 April 2005 and is a first action after a request for continued examination.

#### ***Claim Objections***

1. Claim 10 is objected to because of the following informalities: Claim 10 recites the limitation of "locking of the grip end into the proximal end of the biopsy cannula" positive recitation of the grip end being lockable into the proximal end of the biopsy cannula is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 10 recites the limitation "the direct end of the biopsy cannula" in claim 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US 6,416,484).

Regarding claims 1-7 and 9 Miller discloses a biopsy material holding device (70) for a biopsy cannula insertable into a proximal end of a biopsy cannula and between an inner wall of the biopsy cannula (30) and a tissue-removing (T) to perform transcutaneous biopsies of tissues, said biopsy material holding device comprising a wire (85,81,82,80) having a proximal end, a distal end and a tip (81) at said distal end with beveling arranged at the distal end (best shown in Figure 11), said wire having a pre-stress angle arranged at the proximate end of the wire (as best seen in Figure 10 the wire has an angle  $\alpha_1$ , in order to reduce the crush artifact and core damage, Column 4, Line 52 through Column 5, Line 8) causing the wire including the wire tip to glide along the inner wall of the biopsy cannula when inserted into the biopsy cannula. The biopsy material holding device comprising a grip end (the prismail end 72 of the extractor 70 may be provided with a grasping element 90, see Figure 7 and Column 5, Lines 40-49), wherein said wire is attached to said grip end. The biopsy material holding device further comprising a grip end with an attached extension shank (the body

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74 and 83 ), said and wherein a wire being fastened to the shank (Figures 7 and 8). The biopsy material holding device wherein the bevelling is at the tip, said tip having having a bevelling angle B of 5° to 85° (as best seen in Figure 8 the beveling is arranged at an angle of about 45 degrees) , and being adapted to face the tissue-removing cylinder (Figure 9). The biopsy material holding device wherein the bevelling of the wire is either hollow ground or bulged. The biopsy material holding device wherein said wire is arranged at the center of the grip end (Figure 7 shows the wire arranged at the center of a grip end 90), with the pre-stress angle being between 1° and 90° (Column 5, Lines 1-8). The biopsy material holding device wherein the wire has a length so that the wire reaches the distal end of the biopsy cannula when inserted in the biopsy cannula (see Column 6, Lines 8-29, and Figures 9 and 13). The biopsy material holding device wherein the wire is firmly connected to the distal end of the shank (best seen in Figures 7 and 8) and said pre-stress angle is between 1° and 90° (Column 5, Lines 1-8).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in view of Janese et al. (US 4,781,202).

Miller fails to disclose the device wherein the grip end can be locked into the proximal end of the biopsy cannula. Regarding Claim 8, Janese teaches a biopsy material holding device wherein the grip end can be locked into the proximal end of the biopsy cannula (Figure 1 shows the grip end (proximal end of the wire comprising the handle 10 inside the cannula hub 12 which locks the preventing it from movement perpendicular to the long axis of the cannula 26). Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Miller as taught by Janese in order to prevent movement perpendicular of

the tissue severing device and the cannula.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller, or in the alternative Miller in view of Janese et al. (US 4,781,202).

Miller teaches the device wherein the wire ends at the direct end of the biopsy cannula after insertion of the shank and inserting the grip end into the proximal end of the biopsy cannula. Miller fails to explicitly disclose the wire having a length of 25mm.

The matter of providing a wire with a length of 25mm is a obvious matter of design choice involving the change of size of a component, wherein no unexpected results are obtained over the prior art, the device would still perform the operation of taking tissue samples with reduced crush artifacts, see MPEP 2144.04. The obvious matter of a design choice is supported by Jenese which teaches a biopsy holding device comprising a wire having a bend section wherein the length of the angle to the tip is approximately 13mm and teaches that the size and length of the components can be varied depending on the application, see Column 4, Line 4-17 and Column 5, Lines 10-36). Thus it would have been obvious to a person of ordinary skill in the art to modify the device taught by Miller to have a wire length of 25mm in order to provide a appropriately dimensioned device for a given application as taught by Jenese wherein the only difference is the relative size and has not different function from the prior art.

***Response to Arguments***

11. Applicant's arguments with respect to claims 1-10 are directed towards newly amended claim language and have been considered but are moot in view of the new ground(s) of rejection, presented in the above office action.

***Contact Info***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736